REGULATORY GUIDE B9

COMPLYING WITH TITLE B - VETERINARY FACILITIES

South Carolina Department of Health
and Environmental Control

October 12, 2004

TABLE OF CONTENTS

REGULATORY GUIDE B9
COMPLYING WITH TITLE B - VETERINARY FACILITIES

Each veterinary facility that is registered with the Department is required to comply with Regulation 61-64, X-Rays (Title B), which are the regulations concerning x-ray equipment. This guide is intended to assist the veterinary facility in complying with Title B regulations.

FACILITY REGISTRATION APPROVAL (See RHB 2.4)

Prior to installation the facility must submit the following information to the Department:

- Facility name, location address, and mailing address.
- The name of the Radiation Safety Officer (RSO), who is responsible for radiation protection, and the individual's qualifications to serve in this capacity.
- Type and make of x-ray equipment to be installed.
- Operating policies and procedures. See below under "Operating Procedures".
- A training plan. See below under "Training".
- A shielding plan, if required.
- Shielding review fees must accompany the shielding plan.
- There is a $62.50 non-refundable fee required for registration of new facilities. The application fee must be submitted with the facility registration approval request. The $62.50 should be sent in the form of a check or money order made out to SCDHEC.

.

After review and approval of this information and receipt of application and shielding review fees, the Department will issue a Facility Registration Approval.

REGISTERING EQUIPMENT (See RHB 2.4)

All x-ray equipment is required to be registered with the Department. See Regulatory Guide B1 for assistance in registering equipment. The registrant is also required to report, in writing, any changes that affect his x-ray facility or the x-ray equipment. This includes change of location or mailing address, acquiring or disposing of x-ray equipment, changes in operating procedures that may affect an approved shielding plan, and any changes in the approved training plan or operating procedures.

REQUIREMENTS FOR OPERATING PROCEDURES (See RHB 4.2.4)

All facilities are required to have written operating procedures available to all x-ray operators. It is the responsibility of the registrant to ensure that each operator is familiar with the procedures and competent to operate the x-ray equipment. Documentation must be maintained indicating that each operator has read and agrees to adhere to the operating procedures. The procedures must include the following items, as a minimum:

1) **Policies and Procedures for Patient Holding and Operator Protection.** The procedures must state whether or not, as a matter of policy, animals and/or films will be held at that facility. The availability and use of restraining devices must be addressed. If human holders are used for animals and/or films, then the procedures must address the use of lead aprons and gloves. The process used to select the human holder must be described. Pregnant females should not be used to hold animals and/or films. If animals and/or films are routinely held, the procedures must include how the facility will ensure that no one person is routinely used to hold animals and/or films.

Each veterinary facility must have lead aprons and gloves available in the area of the x-ray unit. The lead aprons and gloves must be at least .5 mm lead and the operating procedures must indicate this lead equivalency will be used. The lead aprons and gloves must be checked annually for cracks and holes that could compromise the radiation protection they provide. This testing must be documented. Records of this testing must be kept for two years or until the next Department inspection.

The procedures must address operator protection. If a permanent or mobile operator's barrier is not used, then the procedures must address the use of lead aprons and gloves, and where the operator will be standing during exposures.

2) **Policies and Procedures for Pregnant Workers.** Procedures to be followed when a worker declares her pregnancy must be included, as well as methods of informing workers of the total exposure received during gestation. If a facility has policies to change the work assignments of pregnant workers, then those policies should be stated. The Nuclear Regulatory Commission's Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers. This guide is available from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20013-7082.

3) **Policies and Procedures for Personnel Monitoring.** Each veterinary facility that holds patients is required to provide personnel monitoring devices. If the human holder's hands are in or near the primary beam, then ring badges must also be provided.

   The operating procedures must state whether or not personnel monitoring devices will be used at the facility. The procedures must tell employees how to correctly use personnel monitoring devices and how to care for personnel monitoring devices. The name of the person responsible for distribution, collection, and records of badges must be stated. The location of control badges must be given. The policies for reporting and investigating over-exposures must be stated. A prohibition against intentionally exposing any control or personnel badge must be included. Procedures must also be included instructing workers on how they may obtain the results from the monitoring.

4) **Procedures for Training New Employees**. See below under "Training."

5) **Methods for Quality Assurance.** The procedures must state the methods that the facility will use to assure that they are producing quality radiographs. This may vary widely from facility to facility. At a minimum, the following items must be addressed in the quality assurance plan: Equipment Performance tests (initial) and Standards for Processing. See below under "Quality Assurance."

PERSONNEL MONITORING (See RHB 4.12.3.2)

Each veterinary facility that holds patients is required to provide personnel monitoring devices. If the human holder's hands are in or near the primary beam, then ring badges must also be provided. In addition, if a declared pregnant worker requests an additional badge for monitoring doses underneath lead aprons, then she must be provided with one.

When a protective lead apron is worn by the operator, and a personnel monitoring device is used, the monitoring device must be worn at the collar outside of the apron. When two monitoring devices are worn (one outside and one under the apron) the one outside will be considered the permanent record for the individual. The Department may

give consideration for the use of protective apparel provided that the registrant submits written procedures to ensure that this apparel is worn at all times. Written procedures must be submitted to and approved by the Department prior to the badge under the apron being used as the permanent record.

The personnel monitoring devices used to determine compliance with occupational dose limits must be processed by a vendor which possesses current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST). The accreditation must be for the type of radiation for which the individual wearing the device is monitored.

Each registrant must maintain records showing the radiation exposure for each person that is required to be monitored. The records must be preserved indefinitely, or until the Department authorizes their disposal. The records may be maintained on microfilm.

PRIOR OCCUPATIONAL EXPOSURE (See RHB 3.20)

Each registrant has the responsibility to require an employee to disclose their previous occupational dose prior to working at the registrant's facility. The registrant must obtain a written, signed statement that states either that the worker had no prior occupational dose during the current calendar quarter or states the nature and amount of any prior occupational dose during the current calendar quarter. For the purpose of this statement, the current calendar quarter is interpreted to mean the most recently available calendar quarter. The registrant must maintain these written statements until the Department authorizes their disposition.

OCCUPATIONAL EXPOSURE AT MULTIPLE FACILITIES (See RHB 3.4.4)

If an employee is likely to receive a dose in excess of 50% of the annual allowable dose, the exposure that an employee receives at any facility must be recorded by each facility at which the employee works. The simplest way to achieve compliance with this requirement would be for an employee to be provided with a monitor to be worn at all facilities where employment occurs, and an individual monitor issued by each facility. Then, total occupational dose could be tracked, as well as doses received at individual facilities.

TRAINING (See RHB 4.12.21)

Each veterinary facility is required by RHB 4.12.21 to ensure that all x-ray operators are adequately instructed in safe operating procedures and competent in the safe use of the equipment. Each operator is also required to have instruction in specific areas. The Department will assess operator training by reviewing the training plan of each veterinary facility. Therefore, each facility must establish a training plan to ensure instruction in the areas specified in RHB 4.12.21. The training plan must document the following items:

1. The topics to be covered during the training period. According to regulations the following items must be addressed as a minimum:
    a) Radiation Protection. Instruction in this area must include:
        1) Characteristics, biological effects, and measurement of x-ray radiation.
        2) Radiation protection standards and dose limits.
        3) Principles of time, distance, and shielding.
        4) Principles of ALARA and methods of dose reduction.
        5) Use of protective clothing.

6) The radiation protection aspects of patient holding.

b) Dark Room Instruction. Instruction in this area must include:
   1) Characteristics and use of x-ray film.
   2) Appropriate methods for processing film.
   3) Care and maintenance of automatic processors, if appropriate.
   4) Use of developing chemicals.
   5) Film storage and protection.
   6) Care of screens and cassettes.
   7) Maintaining an adequate dark room

c) Machine Safety and Operation. Instruction in this area must include:
   1) All aspects of machine functions for which the operator will be responsible, for example the effect of kV and mA on radiographic image.
   2) Safety features and safety procedures associated with the x-ray unit.
   3) How to recognize problems associated with the x-ray unit.
   4) Factors affecting radiographic images.
   5) Specific instruction on the equipment that the operator will use.

d) General Operating Procedures. Instruction in this area must include:
   1) Anatomy as it relates to the types of exams that the operator will be performing.
   2) Patient positioning for the types of exams that the operator will perform.
   3) The proper selection of radiographic techniques.
   4) Proper use of collimating devices.
   5) Design, use, and interpretations of personnel monitoring devices.
   6) The quality assurance procedures in place at the facility, and how to carry out and interpret those procedures.

These topics are the minimum required subjects that must be covered in operator training. They are not necessarily complete for all facilities. Each facility must assess the type of exams that will be performed at the facility, and tailor their training program appropriately. Training must be provided for each type of exam that the operator will be performing, and each type of equipment that the operator will be using.

2. The time frame for which training will be performed for new employees. Training of employees according to the facility's training plan must begin within 30 days after employment.

3. Methods for documenting the training that each operator has received. Documentation on training of operators will be checked at each inspection.

Employees who are licensed veterinary technologists are considered to meet the basic training requirements. Instruction would still be required at each individual facility in areas that may be unique to that facility's operations. Facility specific training would also be required and must be documented for each operator.

Records must be maintained of all training provided to each operator. If the required training was obtained from a seminar or workshop, an agenda of the seminar should be maintained as proof of training. The training records will be checked as part of the routine inspection by the Department. In addition, the Department may request at any time to review the training records of an employee.

QUALITY ASSURANCE (See RHB 4.2.18)

The following items should be checked, at a minimum, for the Department to consider the quality assurance program acceptable. These items are not inclusive of all items that could be addressed in a quality assurance program. Quality assurance programs vary widely from facility to facility, and it is each registrant's responsibility to evaluate the performance of their x-ray imaging systems and tailor their quality assurance plan accordingly. Employees of the facility may or may not be the individuals carrying out the quality assurance monitoring listed below. In most facilities, the quality assurance testing will probably be performed by a combination of the facility and an x-ray vendor. A facility that chooses to have an x-ray vendor perform some or all of the quality assurance monitoring must use a vendor that is registered with DHEC to provide those services. A list of registered vendors is available from the Department.

The following items should be contained in the quality assurance manual, as appropriate:

1) A list of the parameters to be monitored, the frequency of monitoring, and the limits that require corrective action to be taken.
2) A description of the procedures to be used for monitoring each parameter.
3) Procedures to be followed to call problems to the attention of those responsible for correcting them.
4) A list of the records, along with sample forms, that the facility is using. Notations should be made concerning the length of time that each type of record is kept before discarding.
5) Results of acceptance testing of new equipment.

As stated above, the items that must be addressed in a quality assurance plan are (1) equipment performance tests (initial) of the x-ray system, and (2) standards for processing.

1) Equipment Performance Tests of the X-ray System and Associated Components (Calibrations). Written standards must be established for the proper performance of each x-ray imaging system under the registrant's control. These tests are required to be performed at the time of installation, after any major repair, and at any time the Department deems necessary to ensure compliance with the standards. Equipment performance tests must include numerical data. Items found to be non-compliant during these tests must be corrected within sixty (60) days or receipt of the report. Records showing the test results and the correction of non-compliant items found must be retained for five years. If a portable unit is returned to the manufacturer, the unit must be tested once it is returned to the facility. Testing completed prior to return shipment to the facility will not be acceptable.

   The following items, as appropriate, should be included in the x-ray system standards for radiographic equipment. Items marked with an asterisk (*) indicate that this item may be tested by the vendor or the facility.

   - Half-value layer (HVL)
   - X-ray field/light field alignment
   - Exposure reproducibility
   - mA/mAs linearity
   - kVp accuracy
   - Timer reproducibility and accuracy
   - X-ray beam/image receptor centering
   - Collimator light illuminance

- Actual vs. indicated collimator field sizes
- Positive beam limitation function, if provided
- Visual and audible indication of exposure
- Capacitor discharge radiation levels, if appropriate
- Minimum field size
- Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time
- Grid uniformity and alignment
- Integrity of lead aprons, gloves, and other protective clothing *****
- Screen/film contact *****
- Actual vs. Indicated Source to Image Distance (SID), for all clinically used SIDs
- Beam size(s) for fixed collimation, if applicable

These items must be checked upon initial installation and after any maintenance or repair that could affect their status:

- Adherence to the approved shielding plan (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)
- Minimum source to skin distance on mobile radiographic units
- Proper indication of multiple tubes on units so equipped

2) Standards for Processing. The following items should be checked as components of the final diagnostic image obtained. Again, these items are not all inclusive, and should be tailored to meet the individual facility conditions.

a) Evaluation of screens, cassettes, and grids. Procedures should be included for cleaning and maintenance of cassettes and screens and checks of screen condition. Documentation of these cleaning must be kept for 2 years or until the next inspection.

b) Processor quality assurance. The quality assurance plan should address the care, maintenance, and cleaning of the processor, temperature measurement, replenishment rates, water flow rates, and residual fixer testing. Records of processor maintenance must be kept for 2 years or until the next inspection by the Department.

c) Evaluation of darkroom and film. Film base plus fog should be tested, along with darkroom fog conditions. Darkrooms must be light tight to the dark adapted eye, and should be free from dust and dirt. The darkroom must have a functional safelight.

For new facilities, the quality assurance plan will be reviewed by the Department before registration of the x-ray equipment. For existing facilities, the quality assurance plan will be reviewed at the first inspection after the effective date of the regulations. For all facilities, records of quality assurance testing and monitoring will be reviewed on each inspection conducted. Facilities must maintain records of all testing and checks performed.

SHIELDING PLANS (See RHB 4.4)

Before construction, a facility is required to submit a radiation shielding plan and a shielding review fee to the Department for review and approval. The shielding plan must be reviewed by a Class III or a Class IV vendor. After the equipment is installed, "as-built" drawings and the area survey (if applicable) are required to be submitted. See Regulatory Guide B6 for assistance. The shielding plan must be accompanied by a $50.00 Shielding Plan Review fee.

Mobile or portable x-ray units brought inside to be used in a fixed location may require a shielding plan. Please

contact this Department for assistance. Mobile or portable units used permanently in a fixed location will require a shielding plan.

MANUAL FILM PROCESSING (See RHB 4.2.19.1)

When a facility performs manual film processing, the following items are required to be used by the facility:

1) Processing tanks that are mechanically rigid and corrosion resistant.
2) A dedicated darkroom thermometer to measure developer temperature. Developer temperature must be within 60º F and 80º F (16º C to 27º C).
3) A dedicated darkroom timer to set film processing time.
4) Documentation to show when the film processing chemicals are changed.
5) A functional darkroom safelight compatible with the type of film being used.
6) A time-temperature developing chart.

SIGHT DEVELOPING OF RADIOGRAPHS IS NOT ACCEPTABLE FOR PROCESSING FILMS.
The film manufacturer or a vendor registered with the Department should be able to assist facilities in obtaining the items listed above.

AUTOMATIC FILM PROCESSING (See RHB 4.2.19.2)

When a facility uses an automatic processor or other closed processing system, the following items are required:

1) Processing chemical temperatures consistent with the type of film(s) being processed.
2) Appropriate film processing chemicals and replenishment rates.
3) A functional darkroom safelight compatible with the type of film(s) being used.
4) Film immersion times consistent with the developer temperature.
5) The specified developer temperature must be immediately available.

The film manufacturer or a vendor registered with the Department should be able to assist facilities in obtaining the items listed above.

OTHER FILM PROCESSING REQUIREMENTS (See RHB 4.2.19.3)

Film pass boxes must be "light-tight" and incorporate adequate shielding to prevent fogging of undeveloped film from stray radiation. Film must be stored in a cool, dry place protected from stray radiation. Film in open packages must be stored in a light tight container. Film should not be stored where it can be exposed to chemical fumes or radiation. Film that is expired or outdated shall not be used, unless it has been properly stored, and passes a sensitometric test for base + fog, and speed.

Film cassettes and intensifying screens must be inspected in accordance with the facility's approved operating procedures. They must be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality. Documentation of these inspections and cleanings must be maintained for 2 years or until the next inspection by this Department.

Film developing solutions should be properly stored; they should never be allowed to freeze. They must be prepared according to the directions given by the manufacturer, and maintained in strength by replenishment or renewal.

ADMINISTRATIVE REQUIREMENTS

The following items are required to be posted or present at x-ray facilities:

1) Radiation area signs. Each entrance into a radiation area must be posted with a radiation area sign. If it is a high radiation area, then it must be posted with a high radiation area sign. This includes any access from outside the room, such as a restroom with an entrance from a hall and the x-ray room. (See RHB 3.16)

2) Technique charts. (See RHB 4.2.8) A technique chart must be posted at each control panel, which states the following information:

   - The patient's body part and anatomical size versus technique factors to be used.
   - The type and size of film or the film-screen combination to be used.
   - The source to image distance (SID) to be used.
   - For automatic exposure control systems, the appropriate exposure detector(s) must be specified. For automatic exposure control systems, there must also be available a technique chart to be used when the equipment is operated in a non-automatic mode.

3) The x-ray control must have a label on it which states "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed." (See RHB 4.3.1)

OVEREXPOSURES (See RHB 3.25)

The registrant is required to report to the Department any exposure of an individual in excess of any limit in the regulations. The registrant is also required to report any radiation levels in an unrestricted area that are in excess of 10 times any limit in the regulations. The time frame for reporting overexposures depends on the exposure that an individual receives. Immediate, 24 hour, and/or thirty day written notification may be required. See RHB 3.25 concerning radiation levels and the requirements for reporting.

RECORDS

The registrant is required to maintain all records required to comply with or show compliance with Title B. These records include:

- Records showing receipt, transfer, use, storage, and disposal of all sources of radiation. (RHB 1.10.1)

- Records showing model and serial numbers of all tubes, controls, beam limiting devices, vertical cassette holders, and tables. (RHB 1.10.2.1)

- Tube rating charts and cooling curves. (RHB 1.10.2.2)

- Records of aluminum equivalent filtration of the useful beam for all x-ray units, including any routine variation. (RHB 1.10.2.3)

- Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system and components, with the names of persons who performed such services. (RHB 1.10.2.4)

- Copies of all correspondence with the Department. (RHB 1.10.2.5)

- Records of prior occupational dose for employees. (RHB 3.20)

- Records of personnel monitoring results. (RHB 3.22.1)

- Records of employee training. (RHB 4.2.3)

- Results of periodic equipment performance tests of x-ray equipment. (RHB 4.2.18)

- A scale drawing of the x-ray room showing occupancies of surrounding areas, and composition of all walls, or results of an area survey performed by a Class IX vendor showing radiation levels around the room. (RHB 4.4.3)

- Any other records of routine checks or testing that are required to be carried out.

INSPECTIONS

The Department conducts routine periodic inspections of x-ray facilities, on a priority system based on the type of facility that is operating. The Department will also conduct inspections if a complaint is received, or if a facility requests an inspection. If violations are found on an inspection, a follow-up inspection may be conducted if the severity of the violations warrants it. Generally, the Department will send a Notice of Inspection letter to a facility about two weeks in advance of the inspection. Inspections by the Department are mandatory, but every attempt will be made to accommodate patient schedules. The Department does have the right to make unannounced inspections.

The inspection consists of checking the operation of the x-ray equipment, as well as checking administrative items such as records. Generally, an inspection requires use of the x-ray equipment for about one hour per control. The facility can greatly assist the Department inspector by using the attached inspection checklist to ensure that all records are available for review. The checklist also contains some questions that will be asked by the inspector. Having this information readily available at the time of inspection will greatly facilitate the inspection process.

After a facility is inspected, the inspector will conduct an exit interview. The inspector will discuss any items of noncompliance, as well as any other items that the inspector deems relevant. The inspector will leave an inspection report at the conclusion of the inspection. The inspection report will cite any violations of the regulations. The inspector may also make recommendations concerning the x-ray equipment or the facility itself. A facility representative must sign the inspection report acknowledging receipt of the report. All violations are required to be corrected within 60 days of the inspection.

There may be some inspections which may require additional information before they are completed. In these situations, the inspector will send a written report to the facility within approximately two weeks of the inspection. After receiving the report, the facility has twenty days to respond, in writing, to the Department. This twenty day notification must indicate that corrective action will be taken to correct any violations that were found upon inspection. The Department will respond, in writing, to the twenty day notification, and will give a date by which all corrections must be made. The facility must notify the Department, in writing, by this date that corrections have been made.

The facility has the option of correcting recommendations. Each violation and recommendation must be addressed individually. Corrective action must be described for each violation and recommendation. It will not suffice to simply state that all violations and recommendations have been corrected. If a facility chooses not to accept a recommendation made by the Department, the facility should state that in their response. After the Department has received the sixty day notification and reviewed the corrective action, a Completed Corrective Action letter will be sent to the facility.

QUESTIONS

If you have questions, please feel free to call or write:

S.C. DHEC
Bureau of Radiological Health
2600 Bull Street
Columbia, SC 29201
(803) 545-4400
FAX (803) 545-4412

Regulatory Guides

B1 - Registration of X-ray Facilities and Equipment
B2 - Complying with Title B - Medical Facilities
B3 - Complying with Title B - Dental Facilities
B4 - Complying with Title B – Facilities Utilizing Industrial or Analytical Equipment
B5 - Vendor Registration and Responsibilities
B6 - Shielding Plans
B7 - Complying with Title B – Mammography
B8 – Complying With Title B - Bone Densitometers
B9 – Complying with Title B – Veterinary Facilities

Visit our web site at: www. scdhec.net

CHECKLIST FOR DHEC INSPECTION

Please have available the following records for the DHEC inspector:

_____ Personnel monitoring reports.

_____ Records of previous occupational dose for employees.

_____ Documentation of apron testing.

_____ Documentation of operator training.

_____ Records from testing x-ray system performance, initial calibration and service records, as well as in-house testing.

_____ Records from processing quality assurance program, including processor maintenance and cassette/screen cleanings.

_____ A list of all operators of the x-ray equipment. This includes routine operators, as well as back-up operators and part-time operators.

_____ Operating procedures. (Including Patient Holding, Pregnant Workers, Personnel Monitoring, Training, Quality Assurance)

Please be familiar with, and be prepared to show the DHEC inspector the following items:

_____ Posted radiation area signs.

_____ Posted technique charts.

_____ Posted "Notice to Employees"

Other questions the inspector will ask:

1) What brand, type, size, and speed of film do you use?

2) What brand and type of screens do you use?

3) Are films ever held during x-ray exams?

4) Are patients ever held during x-ray exams?

5) Who does servicing on the x-ray equipment?